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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul Dicarlo

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EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

05/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/728,248	Applicant(s) DICARLO ET AL.	
	Examiner RENE TOWA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed January 27, 2009. Claims 1 & 4-33 are pending. Claim 1 has been amended. Claims 2-3 have been cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 4-11, 15 & 20-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,368,045) in view of Kornberg et al. (US 5,197,484), and further in view of Sher (US 5,467,684).

In regards to **claims 1, 15 & 22**, Clement et al. discloses a medical system system, comprising:

- (a) providing a medical system comprising:
 - (i) a housing 8 having a proximal end 10 and a distal end 16;
 - (ii) a stylet 18 having a portion in the housing, the stylet 18 being movable between a first extended position and a first retracted position; and
 - (iii) a cannula 20 coaxially receiving the stylet 18 and having a portion in the housing 8, the cannula 20 being movable between a second extended position and a second retracted position (see figs. 1-2, 3a-d & 4a-4d; column 3/lines 4-16 & 22-32);
 - (iv) a stylet block 36 attached to a proximal end of the stylet 18 and mounted inside the housing 8 (see fig. 2).;
- wherein the stylet block 36 comprises:

a first part inside the housing 8, the first part being moveable between an extended position and a retracted position (see fig. 2).

(b) moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet;

(d) causing movement of the stylet; and,

(e) moving the cannula over the stylet (see claim 19 of Clement et al.).

In regards to **claims 9 & 28**, Clement et al. discloses a medical system further comprising:

a stylet spring 44 capable of moving the stylet 18 from the first retracted position to the first extended position; and

a cannula spring 40 capable of moving the cannula 20 from the second retracted position to the second extended position (see fig. 2).

In regards to **claims 10 & 29**, Clement et al. discloses a medical system further comprising:

a first pivoting latch 52 capable of retaining the stylet 18 in a predetermined position when the stylet 18 is in the first retracted position; and

a second pivoting latch 60 capable of retaining the cannula 20 in a predetermined position when the cannula is in the second retracted position (see fig. 2).

In regards to **claims 11 & 30**, Clement et al. discloses a medical system wherein the stylet 18 comprises a notch 30 with a sharpened leading edge (see fig. 1c).

Clement et al. disclose an system, as described above, that fails to teach a stylet configured to rotate when moved from the first retracted position to the first extended position.

However, with respect to **claims 4-8, 20-21 & 23-27, Kornberg et al.** disclose a biopsy medical system including a cannula 54 having a projection 94 in contact with a track 158 associated with a housing 70;

wherein the track 158 is configured to provide unidirectional rotation to the cannula 54; wherein the track is configured to provide multidirectional rotation to the cannula 54 (see figs. 9,12,17 & 28; column 2/lines 1-9; column 3/lines 39-50 & 52-66; column 4/lines 29-31, 39-42 & 49-61; column 8/lines 18-23 & 25-32; column 9/lines 25-40 & 53-61; column 10/lines 3-6 & 19-24; column 11/lines 27-34 & 46-53; column 12/lines 2-5, 25-32 & 40-47; column 13/lines 19-25; column 14/lines 26-34 & 45-47).

Sher teaches that it is known to provide to simultaneously impart linear and rotational motion onto a piston using a projection and track mechanism such that linear motion of the piston causes rotational motion of the piston (see abstract; see figs. 1-2 & 5; see col. 1, lines 23-41; col. 2, lines 10-33).

In regards to **claims 1, 4-11, 15 & 20-30**, Both Clement et al. and Kornberg et al. teach biopsy systems. Kornberg et al. further teaches that it is known to provide a biopsy system with a driving mechanism comprising a projection and track that can simultaneously rotate and linearly displace a cannula into the body of a patient to obtain a biopsy specimen therefrom, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al.

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with a simultaneously rotating and forwardly driven cannula mechanism as taught by Kornberg et al. in order to automatically rotate the cannula as it penetrates tissue so as to facilitate tissue penetration.

Although Kornberg simultaneously rotates and linearly displaces the cannula by means of torsion spring, Sher teaches that it is known to provide to simultaneously impart linear and rotational motion onto a piston using a projection and track mechanism such that linear motion of the piston causes rotational motion of the piston. Since Clement et al. already teach a system wherein the cannula and stylet are linearly displaced using springs (40, 44), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg with a driving mechanism such that linear displacement of the cannula causes rotational motion of the cannula as suggested by Sher in order to simultaneously rotate and advance the cannula through the tissue.

Similarly, since it is also known to advance and rotate a stylet during a biopsy procedure in order to sever tissue (see figs. 5 & 7-9, and col. 3, lines 30-37, col. 6, lines 27-30, col. 7, lines 3-12 and col. 8, lines 22-29 of US 5,718,237), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg and Sher above with a driving mechanism such that linear displacement of the stylet causes rotational motion of the stylet as claimed in order to automatically simultaneously rotate and advance the stylet through the tissue.

4. **Claims 12, 14, 31 & 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484), Sher ('684), and further in view of Kass (US 5,921,943).

Clement et al. as modified by Kornberg et al. and Sher disclose a system, as described above that teaches all the limitations of the claims except for two openings and an opening opposing the notch.

However, **Kass** discloses a system comprising a stylet including two openings for a notch, which can also be viewed as a notch and an opening opposing the notch (which can be seen in Figure 19) for receiving tissue that has been cut by cutting cannula (see Column 9, lines 15-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Clement et al. as modified by Kornberg et al. and Sher with a notch having two openings and an opening opposing the notch, as taught by Kass, for receiving tissue that has been cut by cutting cannula.

5. **Claims 13 & 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484), Sher ('684), and further in view of Haaga (US 5,394,887).

Clement et al. as modified by Kornberg et al. and Sher disclose a system, as described above that teaches all the limitations of the claims except for a notch comprising a ramped surface.

However, **Haaga** teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the

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tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Clement et al. as modified by Kornberg et al. and Sher with a stylet having a notch with a ramped surface, as taught by Haaga in order to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

6. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484), Sher ('684), and further in view of Burbank et al. (US 6,331,166).

Clement et al. as modified by Kornberg et al. and Sher discloses a system, as described above, that fails to explicitly teach a step of oscillating the stylet along the axis.

However, **Burbank et al.** discloses a system further comprising oscillating the stylet 18 along the axis (see column 7/lines 21-24).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg et al. and Sher with a step of oscillating the stylet along the axis as claimed in order to repetitively drive the stylet into the target tissue.

7. **Claims 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484), Sher ('684), and further in view of Ritchart et al. (US 5,649,547).

Clement et al. as modified by Kornberg et al. and Sher above disclose a system, as described above, that fails to teach the step of collecting a sample in a notch of the stylet.

However, **Ritchart et al.** disclose a system comprising the step of collecting a sample in a notch 28 of a stylet; wherein the system further comprises removing the sample from the notch 28 by inserting an object 22 through an opening located in the notch 28 (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg et al. and Sher with a system step comprising removing the tissue through a notch as taught by Ritchart et al. in order to conveniently collect the severed tissues (see Burbank et al., column 8/lines 39-46).

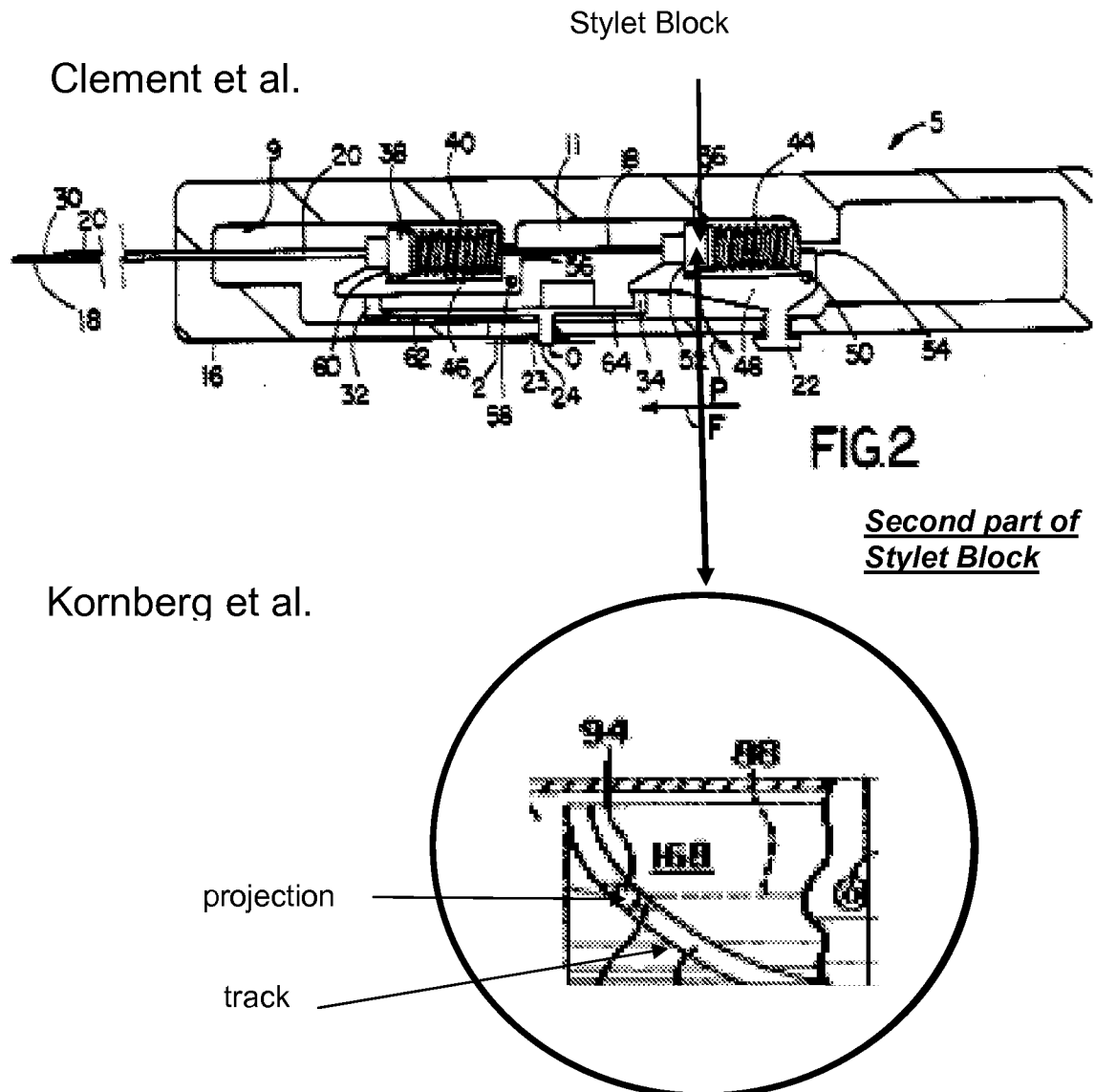
Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg et al., Sher and Ritchart et al. above with a step of removing the sample over an inclined surface as claimed in order to remove the severed tissue.

Response to Arguments

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8. Applicant's arguments filed January 27, 2009 have been fully considered but they are not persuasive. Applicant contends that the prior art fails to teach a second part. This argument has been considered but has not been deemed persuasive.

In response to the Applicant's argument, the Examiner respectfully traverses. The Examiner notes that Clement et al. teach an instrument as described in the rejection supra and reproduced below to facilitate the Applicant's understanding of the Office action.



The Examiner also notes that Applicant's arguments pertain to previous Office actions that have little if any relationship with the Office action dated November 4, 2008; for example, the Office actions have since been withdrawn (i.e. Applicant's footnotes pertain to the Advisory Action dated May 27, 2008, the Office action dated February 25, 2008), and the only footnote pertaining to the Office action dated November 4, 2008 happens to be wrong (i.e. page 2 of the Office action, dated November 4, 2008, never concedes that "Clement does not disclose ...a stylet block as claimed by the applicants").

To the contrary, the Office action dated November 4, 2008, which supersedes all previous communications, asserts in part that Clement et al. teach **a stylet block 36** at page 2 while at page 4, the Office action states that Kornberg et al. disclose a biopsy medical system including **a second part** "having a projection 94 in contact with a track 158 associated with a housing 70; wherein the track 158 is configured to provide unidirectional rotation to the cannula 54; wherein the track is configured to provide multidirectional rotation to the cannula 54 (see figs. 9,12,17 & 28; column 2/lines 1-9; column 3/lines 39-50 & 52-66; column 4/lines 29-31, 39-42 & 49-61; column 8/lines 18-23 & 25-32; column 9/lines 25-40 & 53-61; column 10/lines 3-6 & 19-24; column 11/lines 27-34 & 46-53; column 12/lines 2-5, 25-32 & 40-47; column 13/lines 19-25; column 14/lines 26-34 & 45-47)." As such, the Examiner submits that Clement et al. fully teach a stylet block and Kornberg et al. fully teach a second part comprising a projection and track.

In view of the foregoing, the rejections over at least one of Clement et al., Kornberg et al. and Sher are maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736